REMARKS

Claims 9 and 13 are pending in this application. By this Amendment, claims 9 and 13 are amended. The amendments introduce no new matter. Claim 12 is canceled without prejudice to, or disclaimer of, the subject matter recited in that claim. Reconsideration of the application based on the above amendments and the following remarks is respectfully requested.

Entry of the amendments is proper under 37 CFR §1.116 because the amendments: (a) place the application in condition for allowance for the reasons discussed below; (b) do not raise any new issue requiring further search and/or consideration as the amendments amplify issues previously discussed throughout prosecution; (c) satisfy a requirement of form asserted in the previous Office Action; and (d) place the application in better form for appeal, should an appeal be necessary. The amendments are necessary and were not earlier presented because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

The Office Action rejects claim 12 under 35 U.S.C. §112, second paragraph. The cancellation of claim 12 renders this rejection moot.

The Office Action rejects claims 9, 12 and 13 under 35 U.S.C. §112, second paragraph. The cancellation of claim 12 renders the rejection with respect to this claim moot. The amendments to claims 9 and 13 obviate the rejection with respect to those claims. Accordingly, reconsideration and withdrawal of the rejection of claims 9 and 13 under 35 U.S.C. §112, second paragraph, are respectfully requested.

The Office Action rejects claim 12 under 35 U.S.C. §103(a) over WO/56393 (hereinafter "WO '393") in view of U.S. Patent No. 6,847,847 to Nisch et al. (hereinafter "Nisch"), U.S. Patent No. 7,003,355 to Suaning et al. (hereinafter "Suaning") and "optionally" U.S. Patents Nos. 6,427,087 to Chow et al. (hereinafter "Chow") and/or 2,760,483 to

Tassicker; and rejects claims 9 and 13 under 35 U.S.C. §103(a) over WO '393 in view of Nisch, Tassicker and Suaning. These rejections are respectfully traversed.

The cancellation of claim 12 renders the rejection of that claim moot.

Regarding claim 9, the Office Action concedes that WO '393 does not disclose placing a stimulation electrode between a choroid and the sclera. The Office Action relies on Tassicker to remedy this shortfall. The Office Action asserts that it would have been obvious to one of ordinary skill in the art to modify a placement of the electrode array in WO '393 based on the disk 10 in Tassicker. This conclusion is unreasonable for at least the following reasons.

Tassicker teaches a photosensitive disk that, in response to light entering through the eye, causes change in ionization or ion migration in the various fluids in the adjacent cell structures, resulting in stimulation of either the rods or cones. On illumination, the front of the stimulator assumes a changed potential with respect to the back, and this change in potential results in the change of ionization or ion migration and consequent stimulation (see col. 2, lines 24-45 of Tassicker). The Office Action apparently relies on the configuration depicted in 16b of WO '393 as disclosing a corresponding electrode array outside the retina and an indifferent electrode inside the eye. WO '393 describes the embodiment depicted in 16b as one of the combined electronic and electrode substrate units is positioned subretinally and the other is located epiretinally, and both are held together across the retina so as to efficiently stimulate bipolar and associated cells in the retina.

WO '393 discloses a technique of stimulating a retina by placing a plurality of stimulation electrodes in an eye (on or under the retina) in direct contact with the retina. In WO '393, as shown in Figs. 6 and 7, an indifferent electrode is formed on the back of a substrate on which the stimulation electrodes are arranged, so that the stimulation electrodes and the indifferent electrode are provided adjacently. Thus, WO '393 is premised on the

method of placing the stimulation electrodes in the eye (on or under the retina) so as to come into direct contact with the retina.

The present subject matter is directed to a configuration that an electrode array is put in the inside of a sclerotic flap made by incising part of the sclera so that stimulation electrodes are placed outside a choroid which is on a sclera side, and a reference electrode (an indifferent electrode) extending from a converter is placed in the eye. Thus, the stimulation electrodes and the indifferent electrode are positioned apart and opposite from each other with respect to the retina to allow an electric current to flow between the stimulation electrodes and the indifferent electrode. WO '393 does not reasonably suggest a corresponding structure, even in combination with the other applied references.

As indicated above, WO '393 is arranged to stimulate the retina with the stimulation electrodes (an electrode array 325) held in contact with the retina. Accordingly, even if the electrode array 325 and an electronic chip 320 are connectable through a cable, the cable has to be inserted in an eye tissue (the choroid and the sclera) to actually place the electrode array 325 near the retina and place the electronic chip 320 in the back of the eye. An operation for such a placing would be a very large burden on the operator and a patient. Thus, it appears that WO '393 uses the means for wireless connecting the electrode 325 and the electronic chip 320 in consideration of the difficulty in connecting them with the cable.

On the other hand, the present subject matter discloses that the electrode array (the stimulation electrodes) is placed outside the choroid which is on the sclera side. Accordingly, even by the connection using the cable between the electrode array and the converter, a reduced burden will be applied on an operator and a patient in a surgical operation. Further, since the indifferent electrode is set to extend from the converter placed under the skin of the temporal region of a head, the indifferent electrode is easy to insert in the eye from outside and further the burden on the operator and the patient is reduced.

WO '393 does not disclose a method of operation of allowing an electric current to flow between a corresponding stimulation electrode outside the choroid and an indifferent electrode inside the eye. As depicted in Fig. 16a of WO '393, stimulation is achieved by direct contact of the electrode array with the retina.

Tassiker is addressed to a photosensitive retinal stimulator, such as selenium which has been brought to its photo-active form. The composition, configuration and method of operation of the photo-sensitive disk in Tasasiker cannot reasonably be considered as providing a "predictable result" of the combination of familiar elements according to known methods as applied to WO '393. For example, the results of relocating the electrode array in WO '393 away from direct contact with the retina are not "predictable" based on the divergent, and disfavored, possibility discussed in Tassiker that the photo-sensitive disk may possibly be inserted between the choroid and the sclera. Additionally, modifying WO '393 to include an electrode array between the choroid and the sclera, and an indifferent electrode in the patient's eye by piercing the eye from outside cannot reasonably be considered to have been an "obvious" modification in view of the impermissible change in principle of operation of WO '393 (see MPEP §2143.01(VI)).

The other references are not applied in a manner to overcome the identified shortfalls in the application of WO '393 and Tassiker to the subject matter of the pending claims.

Suaning discloses an example of placing a stimulation electrode 50 on a sclera and placing an indifferent electrode 60 in an eye. However, even if this technique could be combined with the technique of WO '393, it merely teaches that the indifferent electrode connected to the electrode array 325 or the electronic chip 320 of WO '393 is placed in the eye. This would pose similar problems to those discussed above such as difficulty of an operation for placing the indifferent electrode in the eye, and a large burden on an operator and a patient.

On the other hand, according to the present subject matter, the converter and the electrode array (including a number of stimulation electrodes and an electric circuit for distributing stimulation signals to the stimulation electrodes) are provided separately and connected to each other through a cable, and the indifferent electrode is placed extending from the converter. This configuration makes it possible to solve wiring problems due to a number of stimulation electrodes, reduce the burden an the operator and the patient in the surgical operation, and appropriately stimulate the retina through the choroid. These results cannot be reasonably considered as "predictable" based on the teachings of the references as a whole.

Chow discloses an example of using an indifferent electrode. However, this indifferent electrode is provided in a stimulating electrode unit 12 in which stimulation electrodes are placed. Moreover, the ground return electrode unit 16 is not disclosed as placed in the patient's eye by piercing the eye from outside. Of note, the ground return electrode 16 is depicted as only penetrating the neuroretina 50 (see Fig. 5 of Chow). The Office Action also apparently attempts to assert that Suaning inherently teaches placing an indifferent electrode in the patient's eye by piercing the eye from outside. However, Suaning does not explicitly disclose a corresponding feature and it is unreasonable to assert that this feature would necessarily flow from the disclosure of Suaning.

Moreover, as indicated above, it would not have been obvious to one of ordinary skill in the art to modify WO '393 in view of the disclosure of Suaning based on the different principles of operation between these references. In other words, it would not have been obvious to one of ordinary skill in the art to include indifferent electrodes inside the eye and placed apart from the stimulating electrodes in a reference that uses direct contact with the retina to achieve its objects.

Nisch discloses a retina implant for electrically stimulating a retina by incising a sclera and placing a chip from there under the retina (between a retina and the choroids). However, Nisch is arranged such that the chip is inserted from the sclera side to the underside of the retina (between the retina and the choroid), not arranged so that the stimulation electrodes are placed outside the choroid on the sclera side, or in the sclerotic flap.

The present subject matter is configured such that the stimulation electrodes are placed outside the choroid on the sclera side and the indifferent electrode is put in the eye from outside by extending from the converter so as to be placed under the skin of the temporal region apart from the eye. According to this electrical stimulation method, it is possible to facilitate the operation for disposing the stimulation electrodes and the indifferent electrode in place, reducing the burden on the operator and the patient, and allowing the electrical stimulation pulse signals to appropriately flow between the stimulation electrodes and the indifferent electrodes. Thus, the present subject matter yields results that are not merely predictable in view of any familiar elements according to known methods. As argued above, none of the applied references disclose a method of placing stimulation electrodes in a sclerotic flap and outputting the converted electrical stimulation pulse signals having current intensity enough to pass through the choroid and the retina from the stimulation electrodes toward an indifferent electrode inside the eye to electrically stimulate the cells constituting the retina from a choroid side. The patchwork attempt by the Office Action is a conclusion that cannot reasonable be considered to have been obvious based on the disparate disclosures of the applied references.

Claims 9 and 13 are amended to clarify relevant features, for example, claim 9 recites, among other features, the indifferent electrode comprising a wire that is extended from the converter and covered by an insulating material excepting a distal end. Claim 13 recites

similar features. The applied references cannot reasonably be considered to have suggested such features.

For at least the above reasons, the applied references are not combinable in the manner suggested, and no permissible combination of the applied references can reasonably be considered to have suggested the combinations of features positively recited in claims 9 and 13. Accordingly, reconsideration and withdrawal of the rejection of claims 9 and 13 are respectfully requested.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 9 and 13 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

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Attachment:
Petition for Extension of Time

Date: February 11, 2008

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